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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,902	02/13/2002	Gary N. Cherr	309T-300410US	1913

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,902	CHERR ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005 and 25 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,37-39,41-43,45-49,51 and 53-55* is/are pending in the application.

4a) Of the above claim(s) *1-34,38,45-48 and 53-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,37,39,41-43,49 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2005 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed February 6, 2004, and amendment and response to the Final Office Action (mailed April 20, 2004), filed October 25, 2004 wherein claims 35, 37, 39, 43, 49, and 51 have been amended; claims 40, 44, 50, and 52 are cancelled.

Currently, claims 1-35, 37-39, 41-43, 45-49, 51, and 53-55 are pending in this application.

As recorded in the previous Office Action April 20, 2004, Claims 1-34, 38, 45-48, and 53-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 35, 37, 39, 41-43, 49, and 51 as amended now are examined on the merits herein.

Again, Applicant's claim for domestic priority to provisional application Serial No. 60/349,144 filed 01/15/2002, under 35 U.S.C. 119(e) is acknowledged.

The provisional application 60/349,144 upon which priority is claimed, appears to provide adequate support under 35 U.S.C. 112 for the claims in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 39, 41-43, and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment filed October 25, 2004 with respect to these amended claims has been fully considered but is deemed to insert **new matter** into the claims since the specification as originally filed does not provide support for the new limitation "herein the sperm is from a vertebrate, a mammal, a human, a canine, a feline, a rodent, an insect, a fish, an amphibian, or a reptile" (emphasis added)..

The specification as originally filed merely discloses the genus, "a sperm" in original claims, or particular subgenus, and/or specific species, in particular "all mammals, e.g., humans, canines, felines, rodent" or "sea urchin and mammals" (see page 5 lines 1-2 of the specification).

Thus, the specification as originally filed does not provide support for the specific species "an insect, a fish, an amphibian, or a reptile". As noted in MPEP 2163, "a

subgenus is not necessarily described by a genus encompassing it and a species upon which it reads", see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 37, 41-42, 49, and 51 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular sulfonated compound such as a lignosulfonic acid, also known as a lignosulfonate, ligninsulfonate, lignosulfate, or poly(lignosulfonic acid, see the other names of lignosulfonic acid provided by STN Registry, of record), in combination with the only one particular spermicide, Nonoxynol 9™ (see page 6 line 1 of the specification herein) with or without a sperm, in pharmaceutical compositions herein, does not reasonably provide enablement for any sulfonated compounds or "a sulfonated kraft lignin" or "a sulfated lignin" in claims 49 and 51, and any compounds having spermicide function (i.e., in claims 43 and 51).

One skilled in the art would clearly recognize that any sulfonated compounds or any sulfonated compounds isolated from a natural source or any "sulfonated kraft lignin" or "sulfated lignin" would encompass numerous or may be a million different compounds having various structures and possessing very different functional properties or activities. Moreover, the recitation, spermicide, is seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to compositions used for inhibiting fertilization or contraception.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on any sulfonated compounds or any "sulfonated kraft lignin" or "sulfated lignin", and/or any compounds having spermicide function employed in the composition herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case, as discussed above, "spermicide", recited in the instant claims is purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. Moreover, as discussed above, a skilled artisan would clearly recognize that any sulfonated compounds isolated from a natural source would encompass numerous or may be a million different compounds having various structures and possessing very different functional properties or activities. However, the specification merely provides particular sulfonated compounds (e.g., in claims 35 and 37) and one particular compound for spermicide, Nonoxynol 9™.

Thus, the instant specification fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph, since it fails to provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.*

Regarding "a sulfonated kraft lignin" or "a sulfated lignin", it is known that not any sulfonated derivatives of lignin are bioactive or having pharmaceutical activities, but only those ligin-derived macromolecules (LDM) containing lignosulfonate or specific sulfonated (or sulfated) derivatives according to the teachings of Pillai et al. (see abstract and page 140-141, "34" in PTO-1449 submitted November 25, 2002). Cherr et al. also teaches that those low molecular weight polar compounds in the fraction in the isolation of LDM from liginin, are not bioactive (see the bottom of the right column at

page 523, "17" in PTO-1449 submitted November 25, 2002). Thus, not all sulfonated derivatives of lignin have enablement for the instant invention.

Moreover, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any sulfonated compounds isolated from a natural source or any derivatives of a lignin, and any compounds having spermicide function in the pharmaceutical compositions herein.

Further, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a male or a female, or *vivio*) the ***combination*** of any compounds represented by any sulfonated compound isolated from a natural source or any derivative of a lignin, and any compound having spermicide function in a composition. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). Thus, the

teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

It is noted that only two particular sulfonated compounds, a lignosulfonic acid (LSA) and polyanetholesulfonic acid (PASA) were tested in working examples in the specification (see page 21-30). Thus, the specification fails to provide sufficient support of the broad use of any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 41 and 42, and any compounds having spermicide function, recited in the claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions, with no assurance of success.

Response to Argument

Applicant's arguments filed October 25, 2004 with respect to this rejection made under 35 U.S.C. 112, first paragraph, for lack of **full** scope of enablement have been fully considered but are not deemed persuasive. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Moreover, as pointed out in the previous Office Action one skilled in the art would clearly recognize that any sulfonated compounds isolated from a natural source would encompass numerous or may be a million different compounds having various structures and possessing very different functional properties or activities. Moreover, the recitation, spermicide, is seen to be merely functional language. One skilled in the art would understand that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physiological effects and functions.

Further, as discussed in the previous Office Action, regarding "a sulfonated lignin", it is known that not any sulfonated derivatives of lignin are bioactive or having pharmaceutical activities, but only those ligin-derived macromolecules (LDM) containing lignosulfonate according to the teachings of Pillai et al. Cherr et al. also teaches that those low molecular weight polar compounds in the fraction in the isolation of LDM from liginin, are not bioactive as discussed above. Thus, not all sulfonated lignin have enablement for the instant invention.

Furthermore, contrary to Applicant's assertion that "the specification presents guidance such as, e.g., Examples 1-3 and Figure 7, etc., which set out experimental details to help in delineation of possible compounds", notes that only a single particular

sulfonated compound, LSA (a lignosulfonic acid) were tested in Examples 1-3 and Figure 7, and that the other sulfonated compound, polyanetholesulfonic acid (PASA) was tested in working examples in the specification (see page 21-30).

In the instant case, as discussed above, the claims herein especially broadly encompass those unkonown sulfonated compounds isolated from a natural source or those unkonown sulfonated derivatives of a lignin, and/or unknown spermicides, as of the instant filing date. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention, for example, requiring additional or future research to establish or verify any compounds whether having functions recited in the instant claims and their usefulness.

Thus, contrary to Applicant's assertion that "no undue experimentation is needed to do so", the specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement. Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 37, and 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation, "a sulfonic acid derivative of a porphyrin, a sulfonic acid derivative of a triphenylmethane, a sulfonic acid derivative of a stilbene" in the claims herein, render claims 35, 37, 49 and 52 indefinite. These recitations are not defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to "derivatives thereof", since one of ordinary skill in the art would clearly recognize so many various and possible derivatives. Therefore, the scope of claims is indefinite as to the encompassed thereby.

The recitation reasonably reads on any derivatives of lignin which includes bioactive or bio-inactive derivatives and some of derivative of lignin may be harmful or toxic to a mammal being treated.

Given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions. Thus, it is unclear and indefinite as to the "derivative" of compounds herein encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 39, 41-42, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Vines et al. ("A lignin-derived macromolecule inhibits gamete interaction by adhering echinoderm and teleost sperm surfaces", PTO-892).

Vines et al. discloses a composition or compositions comprising ligin-derived macromolecules (LDM) containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, a sulfated lignin, and echinoderm and teleost sperms in an aqueous solution (a pharmaceutical excipient), wherein LDM inhibits gamete interactions by adhering echinoderm and teleost sperm surfaces (see the meeting abstract). Thus, ligin-derived macromolecules (LDM) containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, act as a spermicide.

Thus, the disclosure of Vines et al. anticipates claims 35, 39, 41-42, 49, and 51.

Claims 35, 39, 41-42, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Pillai et al. of record.

Pillai et al. discloses a composition or compositions comprising ligin-derived macromolecules (LDM) containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sea urchin sperm in an aqueous solution (a pharmaceutical excipient) in varying concentrations, wherein LDM may inhibit the sperm acrosome reaction (see page 140, "Introduction" lines 1-4 and the last seven lines of "Introduction", the particular tested samples at page 142, entitled "2.5 Effect of LDM and

electroeluted LDM bands on sperm acrosome reaction" the 1st paragraph, and the last three lines at page 144, and the 2nd paragraph of page 145). It is noted that lignin is known from a woody plant (see the definition of lignin - its ordinary and customary meaning provided by the American Heritage Dictionary, Second College Edition, 1982, page 730, of record; see also US 5,698,524 abstract, of record).

Thus, the disclosure of Pillai et al. anticipates claims 35, 39, 41-42, 49, and 51.

Applicant's remarks filed October 25, 2004 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant's assertion that "Pillai does not teach compositions comprising a pharmaceutically acceptable excipient as recited in each of the instant independent claims, from which the other claims in question depend". Contrary to Applicant's assertion, the aqueous solution of Pillai et al. comprising ligin-derived macromolecules (LDM) containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sperm clearly anticipates the instant compositions since water is a well known pharmaceutically acceptable excipient. Applicant also argues that seawater buffered with glutaraldehyde or paraformaldehyde, are not pharmaceutically acceptable excipients. Note that the transitional phrases "comprising" is employed in the instant claimed composition. Applicant is requested to note that the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03.

In response to Applicant's argument that "the Pillai constituents are for an in vitro assay, not for pharmaceutical use", the instant claims are not limited to in vivo or in vitro. Therefore, it is irrelevant whether the reference includes those features or not. Moreover, note that "LSA Prevents In Vitro Fertilization" in the specification (see Example 2 at page 25 of the specification). Further, a recitation of the intended use of a composition is not considered a limitation of the composition itself. See for example, *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37, 43-44, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vines et al. or Pillai et al. in view of Anderson et al. (6,063,773 of record).

The same disclosure of Vines et al. or Pillai et al. has been discussed above.

Vines et al. or Pillai et al. does not expressly disclose the employment of a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition.

Anderson et al. (6,063,773) discloses that the known spermicide, nonoxynol-9, is known to be useful in a pharmaceutical composition for contraception or inhibiting fertilization. See abstract, col.1 lines 23-32 and col.3 lines 13-16 in particular.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition since both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9, are known to be useful in a composition for contraception or inhibiting fertilization based on the cited prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining a lignosulfonate or a lignosulfonic acid and nonoxynol-9, both known useful for the same purpose, would improve the therapeutic effects for contraception or inhibiting fertilization, and/or would produce additive therapeutic effects in treating the same. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) regarding combination inventions. It is considered prima facie obvious to combine two active composition components into a single composition to form a third composition useful for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. .

Response to Argument

Applicant's arguments filed October 25, 2004 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant's assertion that the there is no motivation to combine the references has been considered but is not found persuasive. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. In the instant case, as discussed in the set forth 103(a) rejection, both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9, are known to be useful in a composition for contraception or inhibiting fertilization based on the cited prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining a lignosulfonate or a lignosulfonic acid and nonoxynol-9, both known useful for the same purpose, would improve the therapeutic effects for contraception or inhibiting fertilization, and/or would produce additive therapeutic effects in treating the same, absent evidence to the contrary.

Applicant's data shown in the Examples 1-3 of the specification at pages 21-30 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art,

since Examples 1-3 provide no clear and convincing evidence of nonobviousness or unexpected results of the claimed combination of a lignosulfonate or a lignosulfonic acid with a spermicide such as nonoxynol-9 over the cited prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
May 23, 2005